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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/601,844
Filing Date: June 23, 2003
Appellant(s): REDDY ET AL.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 20, 2008 appealing from the Final Office action mailed May 24, 2007, and the Advisory Action mailed on March 20, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The following are the related appeals, interferences, and judicial proceedings known to the Examiner, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

(2) Related Appeals and Interferences

The statement of related appeals and interferences contained in the brief is correct.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

Amendment after final was filed on July 20, 2007.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. However, Examiner has withdrawn the rejection, under 35 U.S.C. 112, 2nd paragraph, of Claim 3 for being indefinite for referring to a Figure.

Thus, the only grounds of rejection are (a) 35 U.S.C. 112, 2nd paragraph, rejection for claims 2 and 10, (b) 35 U.S.C. 102 rejections for claims 1-6, and (c) 35 U.S.C. 103 rejection for claims 17 and 18, which are set forth below.

(7) Evidence Relied Upon

(a) US Patent 6,489,329

(b) Tang et al., J.China Pharm Univ 22(4) 2002, pp. 311-312

(c) Pflum et al., Organic Process Research & Devlp. 2001, 5, pp 110-115

(d) Hancock et al., Pharm. Rsearch, Vol. 17, No. 4, 2000.

(8) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

A. 35 U.S.C. 112, 2nd paragraph, rejection for claims 2 and 10.

Claims 2 and 10 were rejected under 35 U.S.C. 112, 2nd paragraph for being indefinite for reciting the term "substantially". The term "substantially" in claims 2 and 10 is a relative term, which renders the claim indefinite. The term " substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of

the scope of the invention. Does substantially free of crystalline forms mean that it is 51 %, 75%, 87% and etc., free of crystalline forms?

Appellant's traversal is not persuasive. On page 4 of the Brief in the first full paragraph, Appellants submit that one skilled in the art would have no difficulty ascertaining the scope of the claimed subject matter in light of the specification. However, the Specification on pages 7-8 only discloses that the compound is "substantially free of crystalline forms". Thus, The term " substantially " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the term "substantially" is indefinite.

B. 35 U.S.C. 102 rejection for claims 1-16.

Claims 1-16 were rejected under 35 U.S.C. 102(b) for being anticipated by Tang et al, Pflum et al, and Van de Venne et al.

Tang teaches the levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 311, Fig. 1 pg. 311, and Figures 2-3 on pg. 312).

Pflum teaches levocetirizine dihydrochloride and falls within the range of Applicant's compounds. (See Abstract, pg. 110, Fig. 1 pg. 110, and Tables 2-3 on pg. 111 and left col.). Additionally, on page 111, left hand column, and on page 112, right hand column (last paragraph), Pflum teaches that the levocetirizine contain yields of 79% and 99%.

Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, and falls within the range of Applicant's compounds. (See Abstract, col. 3 lines 45-60, col. 5, lines 10-55, and Table in col. 6). Since Van de Venne teaches the exact compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Appellant contends, in the paragraph bridging pages 4 and 5 of the Brief, that neither of the references are directed to "amorphous" levocetirizine dihydrochloride, and thus, since the references do not disclose that the compounds are amorphous, Appellant's claims are not anticipated. However, Appellant's traversal is not persuasive.

MPEP 2112 states: "SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY."

The claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)".

In this case, the "unknown property" is the particular crystalline form, i.e., "amorphous". This is unknown because the reference is silent on this property. MPEP further states: "A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but

the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection." Again, the "CHARACTERISTIC", which the prior art is silent is the crystalline form.

This is not an ordinary inherency situation where is it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (See page 1253). The "properties" branch of that statement applies here.

Examiner notes that the USPTO has no testing facilities. If Appellants' reasoning were accepted, then any anticipation rejection of an old compound could always be overcome by tacking on some characteristic or property which the reference was silent, regardless of whether the prior art material was any different from the claimed material. For example, if it did not happen to mention the color, one could patent an old compound just by adding "which is green" or "which is not indigo". One could put in a limitation about density (e.g., density is not 1.4"), melting point, refractive index, solubility, and etc., and then simply point to the silence of the reference, as Appellants have done here. Or one could add properties like or "does not explode on tapping" or "in the form of micro-needles".

Thus, Appellants' Claims are anticipated by Tang et al, Pflum et al, and Van de Venne et al.

C. 35 U.S.C. 103 rejection for claims 17-18.

Claims 17-18 were rejected under 35 U.S.C. 103 for being obvious in view of Van de Venne et al.

Van de Venne teaches compositions comprising levocetirizine dihydrochloride (See Abstract and columns 3-6). The claims differ from the reference by reciting the composition containing a moisture content.

Thus, Van de Venne does not teach Applicant claims in the same format as claimed by applicant, however, one skilled in the art would find the differences in the teaching to be negligible. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Van de Venne to obtain the compositions as claimed in the instant application. Obviousness based on similarity of structure and functions entails motivation to make the clamed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for levocetirizine compositions. See In re Payne, 203 USPQ 245 (CCPA 1979).

Appellant submits, in the paragraphs bridging pages 5 and 6 of the Brief, that the reference is not directed to "amorphous" levocetirizine dihydrochloride, and thus, since the references do not disclose that the compounds are amorphous, Appellant's claims are not obvious. Additionally, Appellant argues that a skilled artisan would not have been motivated to modify Van de Venne to obtain amorphous levocetirizine

dihydrochloride for use in a pharmaceutical composition with a reasonable likelihood of success since amorphous levocetirizine dihydrochloride had not been described, and that amorphous compounds "might" tend to be more soluble than crystalline counterparts. However, Appellant's traversal is not persuasive.

The amorphous form is an obvious variation, which one is motivated to obtain because of the expected solubility advantage. Note this from the conclusion of Hancock, Pharm. Res. 17(4) 397 (2000): "Amorphous pharmaceuticals are markedly more soluble than their crystalline counterparts…Based on a comparison with polymorphic crystal forms of drug compounds the clinical relevance of solubility increases for amorphous drug forms is likely to be significant, even in systems which are only partially amorphous. Additionally, as discussed above, it is clear in MPEP 2112 that "SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY."

The claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)".

In this case, the "unknown property" is the particular crystalline form, i.e., "amorphous". This is unknown because the reference is silent on this property. MPEP further states: "A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection." Again, the "CHARACTERISTIC", which the prior art is silent is the crystalline form.

This is not an ordinary inherency situation where is it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, "There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture." (See page 1253). The "properties" branch of that statement applies here.

Examiner notes that the USPTO has no testing facilities. If Appellants' reasoning were accepted, then any anticipation rejection of an old compound could always be overcome by tacking on some characteristic or property which the reference was silent, regardless of whether the prior art material was any different from the claimed material. For example, if it did not happen to mention the color, one could patent an old compound just by adding "which is green" or "which is not indigo". One could put in a limitation about density (e.g., density is not 1.4"), melting point, refractive index, solubility, and etc., and then simply point to the silence of the reference, as Appellants

have done here. Or one could add properties like or "does not explode on tapping" or "in the form of micro-needles".

Thus, Appellants' Claims are obvious in view of Van de Venne et al.

(9) Response to Argument

The response has been included with the rejection above.

(10) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's Answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Paul V. Ward/
Primary Patent Examiner, Art Unit 1624